

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No.: 7,165,672 :  
:   
Issued: January 23, 2007 :   
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Inventor(s): Fago et al. :   
:   
Assignee: Mallinckrodt Inc. :   
:   
Title: POLYMER PHARMACEUTICAL PIG :   
AND ASSOCIATED METHOD OF USE AND :   
ASSOCIATED METHOD OF PRODUCTION :

**LETTER REGARDING ERROR IN PATENT TERM ADJUSTMENT**

TO THE COMMISSIONER FOR PATENTS,  
SIR:

Pursuant to Comment 43 of the rules listed in Federal Register Vol. 65, No. 181 at page 56387 (Sept. 18, 2000), Patentee hereby notifies the Office that the term adjustment for the patent is longer than appropriate. The Office awarded the patent a term adjustment of four hundred and seventy-eight days (478), but the correct adjustment is zero (0) days.

Patentees filed a PCT Application on October 7, 2003 and completed the requirements for entry in the national stage in the United States under 35 U.S.C. § 371(c) on March 9, 2005 as Application No. 10/527,301. The patent subsequently issued as U.S. Patent No. 7,165,672 on January 23, 2007. A copy of the transaction history retrieved from PAIR for the patent is enclosed.

Under 35 U.S.C. § 154 (b)(1)(A)(i)(II), the date on which an application satisfies the requirements of § 371(c) is used in the calculation of patent term adjustment. The Office incorrectly used March 9, 2003 as the date on which Patentees completed the requirements for entry into the national stage. However, the Office should have used March 9, 2005 in the calculation. Four hundred and seventy-eight days (478) of patent term adjustment were thus incorrectly awarded to Patentees. Using the correct date of March 9, 2005 in the calculation of patent term adjustment results in a determination of zero days (0) of patent term adjustment.

Applicants believe that no fee is due for the filing of this letter.

Respectfully submitted,

Date: Sept 10, 2009



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applicants of this. Likewise, patent term adjustment will not be reduced by applicant actions or inactions (that amount to a failure to engage in reasonable efforts to conclude processing or examination of the application) occurring in a prior (or other) application.

Comment 43: Section 1.705(a) states that the notification of any patent term adjustment under 35 U.S.C. 154(b) will be included on the notice of allowance. One comment asked whether a registered practitioner has an ethical duty to disclose to the Office when the term adjustment indicated is longer period than expected. The comment continues to ask whether attorneys have a similar duty to inform the Office when an examiner indicates subject matter as being allowable with a scope broader than it should be. Finally, the comment asks whether the ethical obligation would be any different if the pre-printed Office form is not used to pay the issue fee and an attorney-generated form is used instead.

Response: The Office currently issues a notice of allowance using the Notice of Allowance and Issue Fee Due (PTOL-85). The Notice of Allowance and Issue Fee Due (PTOL-85) is printed in several parts and one part (PTOL-85B) may be returned with the issue fee payment in order to communicate the assignee and attorney data to be printed on the face of the patent. A registered practitioner is under a general obligation of candor and good faith in practice before the Office. Accordingly, if an examiner suggests claims that the attorney knows are not patentable, Sec. 10.18 precludes the attorney from adopting the examiner's suggestions in an amendment. Similarly, a practitioner signing the PTOL-85B does so pursuant to Sec. 10.18, which means, for example, that if assignee data is provided on the PTOL-85B, the assignee is an assignee of the entire interest in the application, and that the patent term adjustment is correct to the best of his or her knowledge, information and belief, formed after an inquiry reasonable under the circumstances. For example, if a registered practitioner receives determination that the application is eligible for a 1,500 day adjustment and the practitioner is not sure exactly what the adjustment should be, but believes that the adjustment should be 1,000 days, the practitioner does have a duty to disclose the error to the Office, regardless of whether the issue fee is paid using the Office-generated form (PTOL-85B) or an attorney-generated equivalent. In order to comply with this duty and where the correct adjustment is thought to be less than indicated by the Office, an application for term adjustment under Sec. 1.705(b) need not be filed. Instead, a letter could be filed with the issue fee payment, indicating that the term adjustment is thought to be longer than appropriate.

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Comment 44: As to Sec. 1.705(a) one comment asked if the patent term adjustment would be printed in the Official Gazette.

Response: The Office has no plans at this time to add the patent term adjustment to the information printed in the Official Gazette.

Comment 45: As to Sec. 1.705(b), one comment noted that the reference to Sec. 1.704(b) should be a reference to Sec. 1.704.

Response: The suggestion has been adopted in part. The reference to Sec. 1.704(b) has been changed to a reference to Sec. 1.704(a). Section 1.704(a) states that a patent term adjustment shall be reduced by the period of time in which applicant has failed to engage in reasonable efforts to conclude prosecution whereas Sec. 1.704(b) and (c) define when an applicant is determined to have failed to act in such a manner.

Comment 46: As to Sec. 1.705(b), one comment stated that the amount of detail of how the patent term adjustment calculation is made was not stated and urged that the Office provide information as to patent term



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10/527,301

Polymer pharmaceutical pig and associated method of use and production

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## Transaction History

Date	Transaction Description
01-23-2007	Recordation of Patent Grant Mailed
01-03-2007	Issue Notification Mailed
01-23-2007	Patent Issue Date Used in PTA Calculation
12-20-2006	Dispatch to FDC
12-15-2006	Dispatch to FDC
12-14-2006	Application Is Considered Ready for Issue
08-24-2006	Issue Fee Payment Verified
08-24-2006	Issue Fee Payment Received
11-21-2006	Transfer Inquiry to GAU
04-17-2005	371 Completion Date
09-25-2006	Application Return from OIPE
03-09-2005	Additional Application Filing Fees
06-02-2005	Pre-Exam Office Action Withdrawn
08-18-2006	Application Return TO OIPE
08-17-2006	Mail Notice of Allowance
08-17-2006	Mail Examiner's Amendment
08-15-2006	Mail-Petition Decision - Granted
08-11-2006	Petition Entered
06-23-2006	Notice of Allowance Data Verification Completed
06-23-2006	Case Docketed to Examiner in GAU
06-23-2006	Examiner's Amendment Communication
05-15-2006	Date Forwarded to Examiner
05-05-2006	Response after Non-Final Action
05-05-2006	Request for Extension of Time - Granted
05-02-2006	Examiner Interview Summary Record (PTOL - 413)
01-05-2006	Mail Non-Final Rejection
01-04-2006	Non-Final Rejection
06-01-2005	Information Disclosure Statement considered
12-01-2005	Date Forwarded to Examiner
11-29-2005	Response after Non-Final Action
10-07-2005	IFW TSS Processing by Tech Center Complete
08-30-2005	Mail Non-Final Rejection

08-29-2005	Non-Final Rejection
08-26-2005	Case Docketed to Examiner in GAU
06-01-2005	Reference capture on IDS
06-01-2005	Information Disclosure Statement (IDS) Filed
06-01-2005	Information Disclosure Statement (IDS) Filed
03-09-2003	Preliminary Amendment
06-27-2005	Cleared by OIPE CSR
06-02-2005	Application Dispatched from OIPE
06-02-2005	Notice of DO/EO Acceptance Mailed
03-09-2003	Initial Exam Team nn

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